UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514

29755 7590 02/26/2003

FOLEY HOAG LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02110-2600

EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,250	Applicant(s) DANG ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendments filed November 27, 2002 have been entered. The cancellation of claims 42-56 in the amendments filed November 27, 2002 is acknowledged.

Claims 1-41 are pending.

The outstanding rejection of claim 2 under 35 USC 112, second paragraph is withdrawn in view of the remarks filed November 27, 2002.

Applicant is advised that should claim 35 be found allowable, claims 36-38 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 35-38 containing the exact same ingredients in a single composition. Although they are for different use, they are the same composition, which contain the exact same ingredients and components herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18, 21, 23, 28, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-18, 21, 23, 28, and 29 recite the limitation "**all** biocompatible oils" in line 1. There is insufficient antecedent basis for this limitation in the claims. Claim 1 only recites "**a** biocompatible oil", which indicates only one biocompatible oil component is contained in the herein claimed composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 27, 30-33, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Lostritto (Journal of Parenteral Science & Technology from the IDS received February 28, 2002).

Lostritto teaches a flowable composition containing sesame oil 30% and lidocaine HCl 1% (See page 221, col. 1, second to last paragraph).

The viscosity properties and the dielectric constant are inherently possessed by the pharmaceutical composition of Lostritto.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-26, 28, 29, and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lostritto (Journal of Parenteral Science & Technology from the IDS received February 28, 2002) in view of Sonne (US Patent 6,193,985).

Lostritto teaches a flowable composition containing sesame oil 30% and lidocaine HCl 1% (See page 221, col. 1, second to last paragraph).

Lostritto does not expressly teach the amount of lidocaine to be at least 2%, 3% to 80%, 4-67%, at least 10%, or at least 40%. Lostritto does not expressly teach the amount of the biocompatible oil to be at least 33%, at least 50%, at least 75%, at least 85%, or at least 95%. Lostritto does not expressly teach the solvent amount no more than 10%. Lostritto does not expressly teach the composition herein can be incorporated into a kit containing the composition herein and instructions for combining the agents herein.

Sonne teaches a composition containing lidocaine as active and sesame oil as a solvent (See particularly col. 5, line 33; also col. 6, line 51). Sonne also teaches that the composition may be optimized with respect to bioadhesion, sprayability and viscosity as desired (See particularly col. 6, line 47-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed amount of lidocaine, solvent, and

sesame oil in a composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the herein claimed composition and instructions and combine these agents into a kit.

Possessing the cited prior art teaching, one of ordinary skill in the art would have been motivated to employ the herein claimed amount of lidocaine, solvent, and sesame oil into a composition because optimization of therapeutic effect parameters (e.g., amount of the actives) is obvious as being within the skill of the artisan. One of ordinary skill in the art would have been motivated to incorporate the composition herein and instructions for combining the agents into a kit: putting the claimed compositions (lidocaine and sesame oil) together in a kit would be obvious as being within the purview of the artisan. In addition, the inclusion of instructions on how to use a pharmaceutical product, regardless what the indication might be, is mandated by 21 CFR 201.57 and, thus, obvious to one of ordinary skill in the art. Mere inclusion of a specific instruction document with the composition in a kit will not render additional patentable weight to claims drawn to composition kit.

Response to Arguments

Applicant's arguments filed November 27, 2002 averring lidocaine hydrochloride taught by the cited prior art not possessing the recited properties herein claimed have been fully considered but they are not persuasive. Please note that lidocaine hydrochloride is the preferred herein claimed salt of the preferred herein claimed analgesic. Products of identical chemical composition cannot have mutually exclusive

properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical compound, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant's arguments filed November 27, 2002 averring the transitional phrase "consisting essentially of" recited in claim 41 have been considered, but are not found persuasive. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use

of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.") (See MPEP 2111.03).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 11, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

2/24/03